Mifeprex (mifepristone) Information

FDA ALERT [updated 11/2005]: This update provides additional information about four septic deaths in women following medical abortion that were first described by the Food and Drug Administration (FDA) in July 2005. At that time, FDA alerted health care providers that it was aware of four reports of septic death that had occurred in the United States between September 2003 and June 2005 in women following medical abortion with mifepristone (Mifeprex) and misoprostol. Since July 2005, FDA has learned that all four cases of fatal infection tested positive for Clostidium sordelli. FDA tested batches of mifepristone and misoprostol and found no bacterial contamination with Clostridium sordelli. Sepsis is a known risk associated with any type of abortion. The clinical presentation of sepsis in the cases reported here and for which medical information is available was not typical. Please advise patients to contact their healthcare professional if they develop weakness, nausea, vomiting or diarrhea, with or without abdominal pain and fever, more than 24 hours after taking misoprostol. These symptoms, even in the absence of fever, may indicate sepsis.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program at 1-800-FDA-1088 or http://www.fda.gov/medwatch/report/hcp.htm

Recommendations

FDA recommends that healthcare professionals be aware of the following:

- All providers of medical abortion and emergency room health care providers must have an elevated index of suspicion for sepsis in patients who are undergoing medical abortion and present more than 24 hours after taking misoprostol with weakness, nausea, vomiting, or diarrhea with or without abdominal pain, but are afebrile and without physical findings suggestive of infection except tachycardia. Strong consideration should be given to obtaining a complete blood count. Significant leukocytosis with a marked left shift and hemoconcentration may be indicative of sepsis. The CBC results may help identify patients with atypical presentations of serious infection and sepsis versus patients with the normal symptoms of a medical abortion (nausea, vomiting, and cramping pain).

- Physicians should have a high index of suspicion for sepsis so that patients can be immediately treated with antibiotics that include coverage of anaerobic bacteria such as *Clostridium sordellii*.

- At this time FDA does not have sufficient information to recommend the use of prophylactic antibiotics. The risk of fatal sepsis in women undergoing medical abortion is very rare (approximately 1 in 100,000). Prophylactic antibiotic use carries its own risk of

serious adverse events such as severe or fatal allergic reactions. Also, prophylactic use of antibiotics can stimulate the growth of antibiotic resistant bacteria. Finally, it is not known which antibiotic and regimen (what dose and for how long) will be effective.

- The approved Mifeprex regimen for the medical termination of intrauterine pregnancy through 49 days' pregnancy is:
    - Day One: Mifeprex Administration: 3 tablets of 200 mg of Mifeprex orally at once.
    - Day Three: Misoprostol Administration: 2 tablets of 200 mcg of misoprostol orally at once.
    - Day 14: Post-Treatment: the patient must return to confirm that a complete termination has occurred. If not, surgical termination is recommended to manage medical abortion treatment failures.

- The safety and effectiveness of other Mifeprex dosing regimens, including use of oral misoprostol tablets intravaginally, has not been established by the FDA.

Data Summary

FDA is aware of four cases of septic deaths, all reported from California , from September 2003 to June 2005 in women following medical abortion with mifepristone (Mifeprex) and misoprostol. All four cases of fatal infection tested positive for *Clostridium sordellii*. All four cases involve the off-label dosing regimen consisting of 200 mg of oral Mifeprex followed by 800 mcg of intra-vaginally placed misoprostol. FDA testing of batches of mifepristone and misoprostol found no contamination with Clostridium sordelli. The cases of *Clostridium sordellii* for which medical information is available did not have the usual signs and symptoms of an infection: the patients were without fever, and had weakness, nausea, vomiting, or diarrhea with or without abdominal pain. However, they did have significant leukocytosis and hemoconcentration. It is unknown why all four deaths were reported from California, but all providers of medical abortion and their patients need to be aware of the risks of sepsis.

More information is available on the website: http://www.fda.gov/cder/drug/infopage/mifepristone/default.htm. As more information becomes available, FDA will alert the public.

Report serious adverse events to FDA's MedWatch at 1-800-FDA-1088; or www.fda.gov/medwatch/report/hcp.htm

Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
Druginfo@cder.fda.gov

Back to Top Back to Mifeprex

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